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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,402	09/17/2001	Julio Cesar Aguilar Rubido	976-11 PCT/US	3056

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EXAMINER	
SALVOZA, M FRANCO G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,402	AGUILAR RUBIDO ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-18,21-27 and 38-42* is/are pending in the application.

4a) Of the above claim(s) *24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18, 21-23, 25-27 and 38-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Salvoza.

In the paper submitted October 25, 2004, applicants have canceled claim 24 and amended claim 42. Claims 15-18, 21-23, 25-27 and 38-42 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amendment of the claim to "a method of administering a vaccine antigen" is indefinite because it cannot be determined to whom or what the vaccine antigen is being administered to. In addition, it is not clear from the claim what the intended effect of the vaccine antigen administration is or what degree of protection the vaccine antigen mixture is eliciting from the immune system.

This claim as currently amended covers a broad range of activity that would be associated with a method of administering a vaccine antigen, and without any further language it is not clear what the applicant regards as his invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 16 and 21-23 were rejected under 35 U.S.C. 102(b) for being anticipated by Tabor et. al. (U.S. Patent No. 4,547,368) in light of Bowen et. al. (Research in Virology, 1992, 143:269-278, abstract only).

Applicant argues that under a 35 U.S.C. 102(b) rejection, the reference must disclose each and every element of the claim. Additionally, applicant argues that the 35 U.S.C. 102(b) rejection is not appropriate because the equivalency rejection under a combination of Tabor and Owen does not rise to the level of an anticipation rejection, and further, submits references by Thapar et. al. and Ghazi et. al. to demonstrate the variability of immune system responses to antigens administered subcutaneously and mucosally.

Applicant's arguments are considered but are found unpersuasive. First, the use of a combination of references for a 35 U.S.C. 102(b) was proper since the Bowen reference was cited to show that a characteristic not disclosed in the Tabor reference is inherent. This is not an obviousness-type rejection, rather a 35 U.S.C. 102(b) rejection under MPEP § 2131.01 in support of another reference to show an inherent characteristic, namely that the composition of the combination vaccine formulation that is suitable for subcutaneous administration is suitable for mucosal administration as well.

Second, the Tabor reference anticipates applicant's invention since it discloses a vaccine comprising HBsAg and HBcAg. Claim 15 is a product claim drawn to a vaccine formulation or composition, which is anticipated by the Tabor reference, with the Bowen reference cited properly under MPEP § 2131.01 as an inherent characteristic. Judging by the claim language, the product is suitable for mucosal administration, as it is suitable for subcutaneous administration. Tabor teaches that the composition is subcutaneously injected, and a composition that can be subcutaneously administered can also be mucosally administered. The variable effects generated by the immune system in subcutaneous administration versus mucosal administration as cited by the Thapar et. al. and Ghazi et. al. references are tangential to the rejection, which is a 102(b) rejection based upon anticipation of the composition. In addition, the phrase "suitable for mucosal administration" in the claim is a descriptive statement of intended and possible use for the composition, and is only a claim limitation to the extent that it excludes vaccine compositions that *are not* suitable for mucosal administration. Since the claim is drawn to a composition "suitable for mucosal administration" and the Tabor reference cites a composition "suitable for subcutaneous administration," but inherently suitable for mucosal administration as well, the reference meets the limitation of the \ references and the rejection is maintained for reasons of record for claims 15, 16 and 21-23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17, 25, 27 and 38-41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tabor et al. in light of Bowen et al. as applied to claims 15, 16 and 21-23 above, and further in view of Rose et al. (US 6,153,201) and Hauser et al. (US 5,972,346) for reasons of record.

Applicant argued that claim 15, and claims 17, 25 and 27 that depend on it, are patentable for the reasons listed previously. Namely, that there is no disclosure or suggestion of vaccine formulations for mucosal administration comprising HbsAg and HbcAg. Furthermore, applicant argues that claims 38-41 are patentable since the art cited by Examiner Foley of Tabor in light of Bowen and further in view of Rose et. al. and Hauser et. al. do not disclose or suggest vaccine formulations comprising HbsAg and HbcAg for mucosal administration that combine HPV VLP or HBV. Applicant also argues that there is no suggestion in Rose or Hauser to combine HPV VLP with HBV and the vaccine formulation as claimed.

Applicant's arguments are considered but are found unpersuasive. First, claim 15, and claims 17, 25, and 27 that depend on it, are unpatentable for the reasons listed previously. Namely, that the composition is anticipated and the suitability of a composition for mucosal administration is an inherent characteristic that does not exclude suitability for subcutaneous administration. Second, in regards to claims 38-41 to combine a second vaccine antigen and a third vaccine antigen with a mixture of the first vaccine antigen, Hauser states that the hepatitis vaccine composition of the

invention "contains other antigens so that it is effective in the treatment or prophylaxis of one or more other bacterial, viral or fungal infections," see column 3, lines 7-10. The teachings of the Hauser reference are not limited to the preferred embodiments of non hepatitis antigens listed in column 3, lines 11-18. The invention as a whole is drawn to "at least one other component selected from other hepatitis antigens ... or non-hepatitis antigens which are known in the art," see column 3, lines 12-15. One of ordinary skill in the art would have been motivated to use the combination of HBsAg and HbcAg antigens of Tabor in light of Bowen with the HPV VLP of Rose to simultaneously treat hepatitis B and human papilloma virus infections.

Claims 15, 18 and 26 were also rejected under 103(a) for being obvious over Wands et. al. Applicant disputes Examiner Foley's assertion that the administration of the antigen in the fusion protein of Wands et. al. would be equivalent to the simultaneous administration of unfused HBsAg and HCV core antigens in a mixture.

Applicant's arguments are considered but found unpersuasive. Equivalence is intended only as far as the same purpose of asserting antigen presentation to elicit an immune response, but not as to whether or not the processes of administering a product in a mixture would be identical to administering a product as part of a fusion protein.

In the instant case, Examiner Foley made an obviousness rejection by substituting one equivalent process (presentation of a fusion protein comprising HCV and HbsAg core antigens) for another (presentation of HCV and HBsAg core antigens in a mixture). According to MPEP 2144.06, an express suggestion to substitute one equivalent component or process for another is not necessary to render such

substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). For the purposes of antigen presentation to elicit an immune response, one of ordinary skill in the art would be motivated to eliminate the step of using host cell machinery to generate a fusion protein that elicits an immune response. In this respect, the simultaneous administration of unfused HbsAg and HCV core antigens in a mixture would be equivalent to administering the fusion protein of Wands.

Therefore, the invention as a whole would have been prima facie obvious, absent unexpected results to the contrary, and the rejection is maintained for reasons of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvoza
Patent Examiner

JAMES HOUSEL 4/4/05
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